

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

The County of Knott, Kentucky v. Purdue Pharma, L.P., et al

1:18-op-45370-DAP

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**SHORT FORM FOR SUPPLEMENTING
COMPLAINT AND AMENDING
DEFENDANTS AND JURY DEMAND**

Plaintiff submits this supplemental pleading and Amended Complaint incorporating as if fully set forth herein its own prior pleadings and, if indicated below, the common factual allegations identified and the RICO causes of action included in the Corrected Second Amended Complaint and Jury Demand in the case of *The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45090 (“Summit County Pleadings”), *In Re National Prescription Opiate Litigation*, in the United States District Court for the Northern District of Ohio, Dkt #513, 514¹), and as may be amended in the future, and any additional claims asserted herein. Plaintiff also hereby amends its complaint to alter the defendants against which claims are asserted as identified below. To the extent defendants were previously sued in plaintiff(s)’ existing complaint and they are no longer identified as defendants herein, they have been dismissed without prejudice except as limited by CMO-1, Section 6(e). Doc. #232.

¹ Docket #513 is the redacted Summit Second Amended Complaint and Docket #514 is the unredacted Summit Corrected Second Amended Complaint filed under seal in Case No. 1:17-md-02804-DAP. The redacted Summit Corrected Second Amended Complaint is also filed in its individual docket, Case No. 1:18-op-45090-DAP, Docket #24.

INCORPORATION BY REFERENCE OF EXISTING COMPLAINT

1. Plaintiff's Existing Complaint (No. 1:18-op-45370-DAP Doc. #: 1-1) is expressly incorporated by reference to this Short Form as if fully set forth herein except to the extent that allegations regarding certain defendants that are not listed in section 2 below are dismissed without prejudice.

PARTIES – DEFENDANTS

2. Having reviewed the relevant ARCSO data, Plaintiff asserts claims against the following Defendants:

[List all Defendants against which claims are asserted. To the extent a claim is not asserted against a particular defendant, so indicate below. Otherwise each claim will be deemed to be asserted against all Defendants (except for the RICO claims identified below). If Defendants have not been sued previously in Plaintiff(s)' Existing Complaint, Plaintiff must include separate factual allegations below in support of each new defendant and must separately serve each newly named Defendant with notification of the specific ARCSO data that Plaintiffs claim supports the addition of this Defendant pursuant to the Court's Order Setting Procedure for Short Form Amendment of Complaints and Incorporation by Reference of Materials Under Seal]

Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-Mcneil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC F/K/A Actavis PLC²; Actavis, Inc.; Watson Laboratories, Inc.; Insys Therapeutics, Inc.; Actavis LLC; Actavis Pharma, Inc. F/K/A Watson Pharma, Inc.; Endo Health Solutions, Inc.; McKesson Corporation; Cardinal Health, Inc; Amerisourcebergen Drug Corporation; Magna Pharmaceuticals, Inc.; Xanodyne Pharmaceuticals, Inc.; Richie Enterprises LLC D/B/A Richie Pharmacal; SpecGx LLC; Par Pharmaceutical, Inc.; Par Pharmaceuticals Companies, Inc.; West-Ward Pharmaceuticals Corp. k/n/a Hikma Pharmaceuticals, Inc.; Rite Aid of Maryland, Inc.; Rite Aid Corp.; Amneal Pharmaceuticals, Inc. F/K/A Amneal Pharmaceuticals LLC; Smith Drug Company; and H.D. Smith, LLC d/b/a H.D. Smith, f/k/a H.D. Smith Wholesale Drug Company.

I, Joseph Ciaccio, Counsel for Plaintiff, certify that in identifying all Defendants, I have followed the procedure approved by the Court and reviewed the ARCSO data that I understand to be relevant to Plaintiff.

² The list of Allergan-related entities shall be understood to incorporate all affiliates that owned, manufactured, distributed, monitored, or sold opioid medicines at issue, including: Allergan Finance, LLC; Allergan Sales, LLC; Allergan USA, Inc.; Warner Chilcott Company, LLC; Watson Laboratories, Inc.; Actavis Elizabeth LLC; Actavis Pharma, Inc.; Actavis LLC; Actavis Mid Atlantic LLC; Actavis Kadian LLC; Actavis Totowa LLC; Actavis South Atlantic LLC; Actavis Laboratories UT, Inc.; and Actavis Laboratories FL, Inc.

I further certify that, except as set forth below, each of the Defendant(s) newly added herein appears in the ARCos data I reviewed.

I understand that for each newly added Defendant not appearing in the ARCos data I must set forth below factual allegations sufficient to state a claim against any such newly named Defendant that does not appear in the ARCos data.

The following newly added Defendant(s) *do not appear* in the ARCos data I reviewed:

Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.; Stuart D. Baker; John N. Kapoor; Mallinckrodt PLC; Mallinckrodt LLC; CVS Health Corporation; Miami-Luken, Inc.; Noramco, Inc.; Anda, Inc.; Wal-Mart, Inc.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.; and Walgreen Co.

Dated: March, 2019 Signed: /s/ Joseph Ciaccio

Factual Allegations Regarding Individual Defendants

2.1 See enclosed Addendum to Short Form Complaint- Amended of Plaintiff for separate factual allegations againts each newly named defendant.

COMMON FACTUAL ALLEGATIONS

3. By checking the boxes in this section, Plaintiff hereby incorporates by reference to this document the common factual allegations set forth in the *Summit County* Pleadings as identified in the Court's Order implementing the Short Form procedure. Dkt. # 1282

- Common Factual Allegations (Paragraphs 130 through 670 and 746 through 813)
- RICO Marketing Enterprise Common Factual Allegations (Paragraphs 814-848)
- RICO Supply Chain Enterprise Common Factual Allegations (Paragraphs 849-877)

4. If additional claims are alleged below that were not pled in Plaintiff's Existing Complaint (other than the RICO claims asserted herein), the facts supporting those allegations must be pleaded here. Plaintiff asserts the following additional facts to support the claim(s) identified in Paragraph 6 below (below or attached):

Not applicable

CLAIMS

5. The following federal **RICO causes of action** asserted in the *Summit County* Pleadings as identified in the Court's implementing order and any subsequent amendments, Dkt. 1282, are incorporated in this Short Form by reference, in addition to the causes of action already asserted in the Plaintiff(s)'s Existing Complaint (check all that apply):

- First Claim for Relief – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (Against Defendants Purdue, Cephalon, Janssen, Endo and Mallinckrodt (the “RICO Marketing Defendants”)) (*Summit County* Pleadings, Paragraphs 878-905)
- Second Claim for Relief – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (the “RICO Supply Chain Defendants”)) (*Summit County* Pleadings, Paragraphs 906-938)

6. Plaintiff asserts the following **additional claims** as indicated (below or attached):

Not applicable

7. To the extent Plaintiff(s) wish(es) to **dismiss claims** previously asserted in Plaintiff(s)'s Existing Complaint, they are identified below and will be dismissed without prejudice.

Not applicable

WHEREFORE, Plaintiff(s) prays for relief as set forth in the *Summit County* Pleadings in *In Re National Prescription Opiate Litigation* in the United States District Court for the Northern District of Ohio, MDL No. 2804 and in Plaintiff's Existing Complaint as has been amended herein.

Dated: March 15, 2019

/s/ Joseph L. Ciaccio
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ADDENDUM TO SHORT FORM COMPLAINT – AMENDED OF PLAINTIFF COUNTY OF KNOTT

Plaintiff County of Knott, by and through its attorneys, for its *Addendum to its Short Form Complaint – Amended* regarding additional defendants, alleges on personal knowledge as to itself and on information and belief as to all other matters:

NATURE OF AMENDED SHORT FORM COMPLAINT AND ADDENDUM ADDITIONAL PARTIES

A. Purdue-Related Additional Defendants

1. The Purdue-Related Additional Defendants are entities and individuals associated with Purdue Pharma L.P. (“PPLP”), Purdue Pharma Inc. (“PPI”), and The Purdue Frederick Company, Inc. (“PFC”) (collectively “Purdue”). These three entities are members of a worldwide group of associated companies all of which are owned and controlled, directly or indirectly through family trusts and holding companies, 50% by the widow and descendants of Mortimer D. Sackler (“Mortimer Sackler Family”) and 50% by the widow and descendants of Raymond R. Sackler (“Raymond Sackler Family”) (together the Mortimer Sackler Family and the Raymond Sackler Family are referred to as the “Sackler Families”). At all relevant times, the Sackler Families jointly managed and controlled all of the associated companies that the two families owned. Each of the Purdue-related individuals and entities named herein as Additional Defendants knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in the Complaint; none is named merely because of his, her, or its status as a shareholder, limited partner, member of a limited liability company, or beneficiary of a trust.

2. Purdue has been sued by many plaintiffs for the role it played in creating the opioid epidemic. The three Purdue entities originally sued, PPLP, PPI, and PFC, may, however, lack sufficient assets to satisfy their liabilities to those plaintiffs, other creditors, and Plaintiff, because billions of dollars of profits from Purdue’s sale of opioids has been distributed to the

Sackler Families since the 1980s. Accordingly, by this pleading, Plaintiff is adding as defendants those members of the Sackler Families and their controlled entities who knowingly participated in the wrongdoing of Purdue as alleged in the Complaint, and who knowingly received the benefits of that wrongdoing.

3. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the Board of Directors of Purdue and Purdue-related entities..

4. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

5. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

6. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

7. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

8. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

9. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

10. Defendant David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and thus grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

11. Defendant Rhodes Technologies (“Rhodes Tech”) is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

12. Defendant Rhodes Technologies Inc. (“Rhodes Tech Inc.”) is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech. At relevant times, Rhodes Tech Inc. has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

13. Defendant Rhodes Pharmaceuticals L.P. (“Rhodes Pharma”) is a Delaware limited partnership formed November 9, 2007 with its principal place of business in Coventry, R.I. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin which is manufactured by Purdue Pharmaceuticals L.P. (“PPNC”), a Delaware limited partnership, which is a subsidiary of Defendant PPLP and which owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

14. Defendant Rhodes Pharmaceuticals Inc. (“Rhodes Pharma Inc.”) is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin which is manufactured by PPNC.

15. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”) is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related Additional Defendants and the recipient of 50% of the profits from the sale of opioids by Purdue and the Purdue-related Additional Defendants.

16. Defendant The P.F. Laboratories, Inc. (“PF Labs”) is a New Jersey corporation with its principal place of business located in Totowa, New Jersey. It was, at relevant times, engaged in the business of manufacturing OxyContin for Purdue. At all relevant times, PF Labs has been beneficially owned, managed, and controlled by Defendant Sackler Family members.

17. Defendant Stuart D. Baker is a natural person residing in Suffolk County, New York. He has served as a senior executive of, and/or counsel to, Purdue, Purdue-related entities, and members of the Sackler Families since the 1990s.

B. Additional Marketing Defendants

18. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

19. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as “Par Pharmaceutical”). Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. (“EHS”) and Endo

Pharmaceuticals, Inc. (“EPI). EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, “Endo”), manufacture opioids sold throughout the United States including in and around Plaintiff’s geographical area..

20. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

21. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri, and registered to do business around Plaintiff’s geographical area.

22. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, “Mallinckrodt”) manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

23. Defendant Sandoz, Inc. is a Colorado corporation with its principal place of business located in Princeton, New Jersey. It manufactures, promotes, markets, distributes and sells opioids in Plaintiff’s geographic area and throughout the nation.

24. Defendant West-Ward Pharmaceuticals Corp. k/n/a Hikma Pharmaceuticals, Inc. (“West-Ward”). is a Delaware corporation with its principal place of business located in

Eatontown, New Jersey. It manufactures, promotes, markets, distributes and sells opioids in Plaintiff's geographic area and throughout the nation.

25. Defendant Amneal Pharmaceuticals, Inc. F/K/A Amneal Pharmaceuticals LLC ("Amneal") is a Delaware corporation with its principal place of business located in New Jersey. It manufactures, promotes, markets, distributes and sells opioids in Plaintiff's geographic area and throughout the nation.

26. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys develops, markets, and sells prescription drugs, including Subsys, a sublingual spray of fentanyl, around Plaintiff's geographical area.

27. Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."

28. In 2012, Insys received U.S. Food and Drug Administration approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain. However, Insys encountered significant obstacles due to insurers employing a process known as prior authorization. Prior authorization prevents the over prescription and abuse of powerful and expensive drugs. The prior authorization process requires "additional approval from an insurer or its pharmacy benefit manager before dispensing..." and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.

29. Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center ("IRC"), to facilitate the process using aggressive and likely illegal marketing techniques. Insys published education articles that praised their

products' non-addictive nature; and funded patient advocacy groups who unknowingly promoted Insys' agenda of raising the profile of pain so that drugs could be prescribed to treat it. Furthermore, Insys' former sales representatives, motivated by corporate greed, paid off medical practitioners to prescribe Subsys in spite of any medical need. Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.

30. According to a federal indictment and ongoing congressional investigation by Sen. Claire McCaskill, IRC employees pretended to be with doctors' offices and falsified medical histories of patients. The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees implementing these techniques in order to obtain authorization from insurers and pharmacy benefit managers. The transcript reveals an Insys employee pretending to call on behalf of a doctor and inaccurately describes the patient's medical history. For example, Insys employees would create the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys. Insys was warned by a consultant that it lacked needed policies for governing such activities, but the executives failed to implement corrective internal procedures.

31. In a class action law suit against Insys, it was revealed that management "was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon patients were for off-label uses. Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for off-label use.

32. In 2008, biopharmaceutical company Cephalon settled with the U.S. Government for 425 million in a suit against the company that alleged it marketed drugs for unapproved uses (off-label). The FDA approved the drug only for opioid tolerant cancer patients. According to the Oregon settlement and class-action lawsuit, at least three employees involved in sales and/or marketing at Cephalon had moved over to Insys Therapeutics.

33. Additionally, Insys created a “legal speaker program” which turned out to be a scam. The Justice Department commented on the program and stated:

34. The Speaker Programs, which were typically held at high-end restaurants, were ostensibly designed to gather licensed healthcare professionals who had the capacity to prescribe Subsys and educate them about the drug. In truth, the events were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and no educational component took place. “Speakers” were paid a fee that ranged from \$1,000 to several thousand dollars for attending these dinners. At times, the sign-in sheets for the Speaker Programs were forged so as to make it appear that the programs had an appropriate audience of healthcare professionals.

35. Insys paid hundreds of thousands of dollars to doctors in exchange for prescribing Subsys and three top prescribers have already been convicted of taking bribes.

36. Fentanyl products are considered to be the most potent and dangerous opioids on the market and up to 50 times more powerful than heroine.

37. In an internal presentation dated 2012 and entitles, “2013 SUBSYS Brand Plan,” Insys identified one of six “key strategic imperatives” as “Mitigate Prior Authorization barriers.” On a later slide, the company identified several tasks associated with this effort, including “Build internal [prior authorization] assistance infrastructure,” “Establish an internal 1-800

reimbursement assistance hotline,” and “Educate field force on [prior authorization] process and facilitation.”

38. Additional materials produced by Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, “Insys Call Note, Email, & IRC Verbatim Data Audit Report.” The introduction to the report explained that “CIS was approached by INSYS’ legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented.” Insys had expressed concerns “with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements.” An additional concern “stemmed from the lack of monitoring of commercial activities where these types of interactions could occur.”

39. Given these issues, Insys requested that CIS review—in part—“the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers … to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS’ commercially marketed product.”

40. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, “[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers

(HCIs)], or patients exists...that governs the support function of obtaining a prior authorization for the use of SUBSYS.”

41. In addition, the report noted that “there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC.”

42. In fact, “[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast.”

43. Although four informal standard operating procedures existed with regard to IRC functions, these documents “lacked a formal review and approval” and failed to “outline appropriately the actions performed within the IRC.”

44. The report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, “no formal, documented, or detailed processes by which IRC representatives’ calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner.”

45. More broadly, the report notes that “no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients.”

46. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management “formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs.”

47. Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures “specific to each job function within the IRC,” accompanied by “adequate training and understanding of these processes.” To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management “to monitor both live and anonymously IRC employee communications both incoming and outgoing.” Finally, CIS recommended that Insys institute a formal process for revising and updating “IRC documentation used for patient and HCP data.”

48. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed “that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated.”

49. Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee’s affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

50. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”

51. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

52. Defendant John N. Kapoor is a resident of Phoenix, Arizona and was the founder and owner of Insys Therapeutics, Inc. He held various executive positions at Insys including Chairman of the Board of Directors and CEO. In 2013, *Forbes* Magazine listed him as a

billionaire following the success of Insys' initial public offering. In 2017, Kapoor, along with other Insys executives, was arrested and charged by the Office of the United States Attorney for the District of Massachusetts, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies.

53. Defendant Kapoor personally directed the activities of Insys, including, upon information and belief, the payment of fraudulent kickbacks to prescribers in Kentucky, and directed the misrepresentations to third party payors to obtain off-label coverage of Subsys.

54. Defendants Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Stuart Baker, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., Raymond Sackler Trust, PF Labs, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Mallinckrodt plc, Mallinckrodt LLC, SpecGx LLC, Insys, Noramco, and John Kapoor are "Marketing Defendants" as used in the Summit County Complaint. Plaintiffs adopt all allegations and causes of action alleged against the Marketing Defendants in the Summit County Complaint against these defendants as if fully set forth herein.

C. Additional Wholesale and Retail Distributor Defendants

55. Defendant Anda, Inc. ("Anda"), is a Florida corporation with its principal office located in Olive Branch, Mississippi and is registered to do business in and around Plaintiff's geographical area.. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") acquired Anda for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in and/or around Plaintiffs' geographical area.

56. Defendant Smith Drug Company (“Smith Drug”) is a South Carolina corporation with its principal place of business in South Carolina. Smith Drug, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

57. At all times relevant to this Complaint, Smith Drug distributed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

58. Defendant H.D. Smith, LLC d/b/a H.D. Smith, f/k/a H.D. Smith Wholesale Drug Company (“H.D. Smith”), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff’s Community. H.D. Smith is registered to conduct business and/or conducts business in Plaintiff’s community as a licensed wholesale pharmaceutical distributor under the following named business entities: H.D. Smith Wholesale Drug Company, H.D. Smith Holdings, LLC, and H.D. Smith Holding Company. H.D. Smith Wholesale Drug Company has been restructured and it is currently doing business as H.D. Smith, LLC.

59. H.D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H.D. Smith. H.D. Smith is a distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware limited liability company with its principal place of business in Springfield, Illinois. At all times relevant to this Complaint, H.D. Smith distributed prescription opioids throughout the United States, including in Plaintiff’s Community specifically. H.D. Smith distributed opioids, in violation of the duties owed to Plaintiff as set forth in Plaintiff’s original complaint and the other

allegations incorporated herein, in sufficient quantities to be a proximate cause of Plaintiff's injuries. H.D. Smith is sued as a Distributor Defendant.

60. Defendant CVS Health Corporation ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores, including in and around Plaintiff's geographical area., that sell prescription medicines, including opioids.

61. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiff's geographical area..

62. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc. is a Delaware corporations with its principal offices located in Camp Hill, Pennsylvania.

63. Defendant Rite Aid Corp. is a Delaware corporations with its principal offices located in Camp Hill, Pennsylvania. Together, Rite Aid of Maryland, Inc. and Rite Aid Corp. are referred to as "Rite Aid."

64. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in and around Plaintiff's geographical area that sell prescription medicines, including opioids.

65. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the

retail selling of opioids throughout the United States, including in and around Plaintiff's geographical area..

66. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois.

67. Defendant Walgreen Eastern Co. is a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids. Defendant Walgreen, Co. is a subsidiary of Walgreens Boots Alliance that operates retail drug stores.

68. Together, Walgreens Boots Alliance, Inc., Walgreen Eastern Co. and Walgreen Co. are referred to as "Walgreens."

69. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiff's geographical area.

70. Defendant Wal-Mart Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiff's geographical area..

71. In their capacity as wholesale distributors, Anda, CVS, Rite-Aid, Walgreens, and Wal-Mart are "Distributor Defendants" as used in the Summit County Complaint. Plaintiffs

adopt all allegations and causes of action alleged against the Distributor Defendants in the Summit County Complaint against these defendants as if fully set forth herein.

72. Defendant Miami-Luken, Inc. (“Miami-Luken”) is an Ohio corporation with its headquarters and principal place of business in Springboro, Ohio. At all times relevant to this Complaint, Miami-Luken distributed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

73. To the extent they are sued with respect to their activities as retail sellers of prescription opioids, CVS, Rite-Aid, Walgreens, and Wal-Mart are referred to herein as “Retail Chain Pharmacies” or “Retail Chain Pharmacy Defendants.” The allegations pertaining to the Retail Chain Pharmacies that form the basis of Plaintiff’s claims against these defendants are set forth below.

ALLEGATIONS PERTAINING TO ADDITIONAL DEFENDANTS

A. The Purdue-Related Additional Defendants Participated in and Profited from Purdue’s Wrongdoing

(1) Structure of the Purdue Entities and the Roles of the Individual Purdue-Related Defendants

74. At all relevant times, the Sackler Families – in particular, as detailed below, Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Beverly Sackler, Thereas Sackler, Ilene Sackler Lefcourt, David Sackler, and Raymond Sackler Trust (“Sackler Defendants”) – controlled Purdue and its associated companies. Purdue is part of a complicated web of entities through which the Sackler Families operate. PPI is the managing general partner of PPLP and of many of the various Purdue-related entities. Its status as managing general partner of the various entities ensures PPI’s control of those entities. In turn, at all relevant times, all of the members of the board of PPI have been members of the Sackler Families or Sackler-family retainers. The Purdue-related Additional Defendants that are not controlled by the

Sackler Defendants through PPI are controlled by them through different entities unknown to Plaintiff.

75. Because the Sackler Families control of the board of PPI, the officers of PPI and PPLP reported to them. This ensured Sackler control of PPI and PPLP, even when the officers of those entities were not themselves members of the Sackler Families.

76. The Sackler Defendants are beneficial owners of, and exercise complete control over, all four Rhodes Defendants and PF Labs.

77. The Sackler Defendants made the decision that the Sackler Families should enter the generic market for OxyContin in or about 2008 and that it should do so through Rhodes Pharma, a Sackler-owned entity created for that purpose.

78. The Sackler Defendants caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families hundreds of millions of dollars of profits earned by Purdue and its associated companies from the sale of opioids.

79. Each of the Sackler Defendants named herein has served on the board of directors of, or as an officer of, Purdue and one or more Purdue-related Additional Defendants.

80. The Sackler Defendants beneficially own and control all of the entities owned by the Sackler Families, including PF Labs and the Rhodes Defendants, in substantially the same way as they control PPLP and its affiliates, although they may do so using different holding companies and trusts than those used to control PPLP.

81. At all relevant times, Richard Sackler played an active and central role in the management of Purdue and the Purdue-related Additional Defendants. He began working for Purdue as Assistant to the President (his father, Raymond) in the 1970s. He later served as Vice President of Marketing and Sales. In the early 1990s he became Senior Vice President, which

was the position he held at the time OxyContin was launched in 1996. In 1999, he became President, and he served in that position until 2003.

82. Richard Sackler resigned as President in 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve, with his uncle Mortimer, as Co-Chair of the Board of Purdue. In that way, among others, the family maintained control over their family business, even though they were no longer officers, because the officers reported to them.

83. As a senior executive of Purdue, Richard Sackler was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioid products, including OxyContin. He worked tirelessly to make OxyContin a blockbuster, telling colleagues how devoted he was to the drug's success. Along with his father (Raymond) and his uncle (Mortimer), he launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by his uncle Arthur. Within five years of its introduction, OxyContin was generating a billion dollars a year. When OxyContin met with resistance, Richard participated in Purdue's efforts to counter that resistance.

84. At all relevant times, Richard Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and the Purdue-related Additional Defendants.

85. Richard Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related Additional Defendants named herein as additional defendants from the sale of opioids.

86. Jonathan Sackler was a Vice President of Purdue in 1991, and by 2000 he was a Senior Vice President. Like his brother Richard, he resigned that position in or after 2003,

apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the board of Purdue.

87. At all relevant times, Jonathan Sackler served as a trustee or one or more trusts that beneficially owns and control Purdue and the Purdue-related Additional Defendants.

88. Jonathan Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids.

89. Mortimer D.A. Sackler served as a Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. He resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the Board of Purdue.

90. Mortimer D.A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids.

91. Kathe A. Sackler was a Vice President of Purdue in 1991, and by 2000 she was a Senior Vice President. She resigned that position in or about 2003 due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

92. Kathe A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids.

93. Ilene Sackler Lefcourt served as Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. She resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

94. Ilene Sackler Lefcourt is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids.

95. At all relevant times, Beverly Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and the Purdue-related Additional Defendants and to which 50% of the profits of Purdue and the Purdue-related Additional Defendants from the sale of opioids has been conveyed. She has also served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

96. Beverly Sackler is the direct or indirect beneficiary of some portion of 50% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids.

97. Theresa Sackler is the direct or indirect beneficiary of 50% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids. She has also served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

98. David A. Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids. He has also served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

99. Stuart Baker joined Purdue in 1994 as Executive Vice President of PPLP and as Vice President of PF Co. He served as legal counsel to the entire Purdue organization and the Sackler Families. He also served as an officer of other Sackler-owned, Purdue-related entities. He served as a trustee of one or more trusts that beneficially own and control Purdue and the Purdue-related Additional Defendants. He served as Corporate Secretary for Purdue, and as such he gained direct knowledge of the wrongdoing alleged in the Complaint. In his capacity as an

officer, director, and lawyer, he knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in the Complaint and knowingly aided and abetted the Sackler Families, and the Purdue-related Additional Defendants, to structure their personal affairs and the personal and business organizations they beneficially owned and controlled in such a way as to attempt to evade personal liability for the wrongdoing in which he knew they had engaged and in which he knew they intended to continue to engage.

100. The Sackler Families are the sole beneficial owners of Purdue and its associated companies and the Purdue-related Additional Defendants. All of Purdue's and its associated companies' profits go to Sackler-family trusts and entities.

101. Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., the Raymond Sackler Trust (through its trustees), P.F. Labs, and Stuart D. Baker each knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in the Complaint.

(2) The Sacklers and the Integration of Advertising and Medicine

102. As set forth in the Complaint, before the defendants in this action began their marketing campaign for prescription opioids, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance. The commercial success of prescription opioids thus would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

103. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of Arthur Sackler, the (now-deceased) brother of Raymond and Mortimer Sackler.

104. Arthur Sackler created the pharmaceutical advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

105. Arthur Sackler, a psychiatrist turned “ad man,” was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician “education” in the form of seminars and continuing medical education courses. He understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

106. Arthur Sackler revolutionized medical marketing in the 1950’s and 60’s by creating the very marketing ploys his family later used to perpetuate the massive fraud alleged in this action. In striving to make Pfizer (with its blockbuster drug, valium) a household name among physicians, Arthur Sackler recognized that “selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription,” and he maximized influence over physician prescribing by developing the following marketing ploys to disseminate pharmaceutical messaging to the masses under the guise of science and truth:

- a. contacting prescribers directly with a variety of perks, benefits and even job offers;

- b. publishing seemingly neutral articles in medical journals, citing scientific studies (frequently underwritten by the pharmaceutical companies whose products he was marketing);
- c. marketing illnesses (i.e., lamenting and marketing the under treatment of purported illnesses and the corresponding under-utilization of drugs he was promoting);
- d. paying prominent physicians to endorse his products; and
- e. funding continuing medical education programs (“CME’s”), controlling the messaging of key opinion leaders, and maximizing influence over physician prescribing practices.

107. In the 1960s, Arthur Sackler made Valium into the first hundred-million-dollar drug, so popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was one of the keys to his success. When Arthur’s client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially stress—and pitched Valium as the solution. The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

108. In marketing tranquilizers Librium and Valium, Arthur Sackler broadened his customer base to potentially include everyone. For example, one campaign encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever, urging doctors to “consider the usefulness of Valium” in patients with *no* demonstrable pathology. Such marketing led one physician, writing in the journal *Psychosomatics* in 1965, to ask, “When do we *not* use this drug?”

109. As the line between medical education and medical marketing became very deliberately blurred, Valium became the pharmaceutical industry’s first hundred-million-dollar,

and then billion-dollar, drug. For his design and creation of these medical marketing strategies, he was posthumously inducted into the Medical Advertising Hall of Fame, but as succinctly put by Allen Frances, the former chair of psychiatry at Duke University School of Medicine: “*Most of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler.*”

110. In other precursors of the current crisis, Arthur Sackler promoted these drugs despite the lack of any studies of their addictive potential. Additionally, he started his own newspaper, the *Medical Tribune*, despite concerns that a pharmaceutical advertiser should not be publishing a medical periodical directed at doctors. He paid Key Opinion Leaders (“KOLs”), including for example, Henry Welch (then chief of FDA’s antibiotics division), almost \$300,000 in exchange for his help in promoting pharmaceutical drugs. By the 1970’s, doctors were prescribing more than 100 million tranquilizer prescriptions annually, creating what Sen. Edward Kennedy called ““a nightmare of dependence and addiction.””

(3) **The Sackler Families and the Development of OxyContin**

111. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company (“PF Co.”) in 1952.

112. PF Co. had been formed in 1892 by Dr. John Purdue Gray and George Frederick Bingham and incorporated in New York on June 29, 1911.

113. After Arthur’s death, Mortimer and Raymond bought out his share. Since that time PF Co. and its associated companies have all been owned by the Raymond Sackler Family and the Mortimer Sackler Family.

114. PF Co. is no longer an active New York corporation, having been merged into PF Labs on May 7, 2004.

115. At all relevant times, PF Co. and PF Labs have been beneficially owned by the Sackler Families and controlled by them through Defendant Sackler Family members.

116. After the Sackler brothers acquired PF Co. in 1952, they sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur was not involved, on paper at least, in running the family business because that would have been a conflict of interest. Raymond became the head executive of the family's US business while Mortimer ran the UK side of the business.

117. Beginning in the 1980s PF Co. and its associated companies engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing opioids throughout the United States.

118. In the 1980s, the Sackler Families, through a UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. PF Co. marketed this extended-release morphine as MS Contin. It quickly became the Sackler Families' best seller. As the patent expiration for MS Contin loomed, the Sackler Families searched for a drug to replace it. Around that time, Richard Sackler had become more involved in the management of the families' businesses. Richard had grand ambitions for the family business; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big." Richard believed Purdue should develop another use for its "Contin" timed-release system.

119. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen combination

pill, or Percodan, where it was blended with aspirin. By contrast, the oxycodone pill developed by Purdue – OxyContin -- was pure oxycodone in a time-release formula similar to MS Contin, and it was more potent than morphine. Purdue also decided to produce pills with as much as 160 milligrams of oxycodone, far in excess of any other prescription opioid.

120. OxyContin was created by PF Co., but responsibility for designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and distributing OxyContin and other opioid products was shared among PF Co., Purdue, PF Labs, and other Purdue-related companies.

121. At relevant times, OxyContin was manufactured by PF Labs.

122. MS Contin had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what is more, it was sometimes mistakenly called “oxycodine,” which also contributed to a false perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this false perception to its advantage when it eventually pled guilty to criminal charges of “misbranding” in 2007, admitting that it was “well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine” and “did not want to do anything ‘to make physicians think that oxycodone was stronger or equal to morphine’ or to ‘take any steps . . . that would affect the unique position that OxyContin’” held among physicians.

123. Even though oxycodone did not have the same stigma as morphine, in focus groups conducted before OxyContin’s release, Purdue learned that doctors were concerned about the abuse potential of opioids. The focus group concluded that the perceived abuse potential of opioids was the “‘biggest negative’ that might prevent widespread use of the drug.”

124. For Purdue and OxyContin to be “*really big*,” Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug’s uses beyond cancer pain and hospice care. A marketing memo sent to Purdue’s top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

125. Despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, “There are 50 million patients in this country who have chronic pain that’s not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that.”

(4) **Purdue’s Officers and Directors Knew About, and Participated in, Purdue’s Wrongdoing**

126. The members of the board of Purdue were intimately involved in the activities of the entities that they managed, often on a weekly or even daily basis.

127. Purdue, PF Co., PF Labs, and the Sackler Families launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by Arthur. They trained and armed a force of approximately 1,000 sales representatives with charts showing OxyContin’s purported benefits. A major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or for cancer pain but also for less acute, longer-lasting pain, such

as arthritis, back pain, sports injuries, fibromyalgia. The number of conditions that OxyContin could treat seemed almost unlimited.

128. The training included "training in 'overcoming objections' from clinicians." "If a doctor inquired about addiction," the representative was instructed to respond thus: "'The delivery system is believed to reduce the abuse liability of the drug.'" Another sales representative said that Purdue executives "told us to say things like it is 'virtually' non-addicting."

129. Purdue sales representatives were provided with studies and literature provided by other physicians. Purdue had a speakers' bureau through which it paid several thousand doctors to attend medical conferences and deliver presentations about OxyContin's merits. "Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton." Internal documents reflect that doctors who attended these seminars wrote OxyContin prescriptions more than twice as often as those who didn't.

130. Purdue also advertised in medical journals and produced promotional videos featuring not just satisfied patients but also doctor's testimonials. "The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company."

131. According to a former OxyContin sales representative, Richard Sackler was "'the dude that made it happen.'" Richard Sackler himself was tireless in his dedication to OxyContin's success. When benefit plans began citing OxyContin abuse as an excuse not to pay, Richard Sackler sent an email to sales representatives stating that, for insurers, "'addiction' may be a convenient way to just say 'NO.'"

132. Members of the Sackler family were daily on site at Purdue's headquarters, controlling the management of their family business and all of its employees.

133. Richard Sackler is named as inventor on some 50 patents relating to oxycodone and other pain medications, including several patents apparently issued as late as 2016. Virtually all such patents invented by Richard Sackler were assigned to Purdue.

134. In 1997, both Richard and Kathe Sackler were part of a conspiracy to deceive physicians into believing that oxycodone was half as strong as morphine, when in fact the opposite was true; this deception was known by Purdue to ease the fears of well-meaning and careful physicians about prescribing OxyContin for non-cancer pain uses.

135. In the late 1990s Richard, Jonathan and Kathe Sackler participated in an unlawful attempt to deceive European drug regulators into classifying OxyContin as totally uncontrolled, i.e., capable of being obtained without a prescription, despite the fact that all of these family members were by then well aware of the abuse liability of the drug in the U.S.

136. In 2001, Kathe Sackler attended a talk given by the chief medical officer of Sikorsky Aircraft, in which the speaker expressed grave concern about the risks associated with OxyContin; instead of acknowledging this fact to the medical officer, Kathe Sackler instead remained silent and returned to the Purdue headquarters, where employees were directed to find ways to undercut and deflect the Sikorsky medical officer's concerns.

137. In the period around 1999-2003, Purdue developed a method to cause company emails to self-destruct at a pre-determined time; this was an attempt to create a system where potentially incriminating documents would automatically self-destruct, even after receipt by unrelated third-parties. Richard, Jonathan and Kathe Sackler all were directly aware and supportive of this project.

(5) **Members of the Sackler Families Were Aware of Risks Associated With OxyContin No Later Than the Summer of 1999**

138. That prescription opioids would lead to addiction, and specifically that OxyContin could be, and was being, abused has been known to Purdue and to the members of the Sackler Families involved in running the family business since at least the summer of 1999.

139. In summer of 1999, a Purdue sales representative wrote to the President of Purdue reporting widespread abuse of OxyContin. As a result of that memo, a secretary at Purdue, Maureen Sara, was tasked with doing research on the Internet to learn about the nature and scope of the abuse, specifically to learn about how recreational drug users were misusing OxyContin.

140. In order to carry out her assignment, Ms. Sara began visiting drug-user Internet "news groups" or "chat rooms" on a daily basis. Two groups in particular that Ms. Sara visited were alt.drugs and alt.drugs.hard. For a period of time, in the late summer and early fall of 1999, Ms. Sara would forward screen shots from these news groups on a daily basis to Howard Udell, then General Counsel of Purdue.

141. In October or November, 1999, Ms. Sara prepared a memo summarizing her research into misuse of OxyContin. The memo described how users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them. Ms. Sara sent the memo containing the details of OxyContin abuse by drug users not only to the President of Purdue and to its General Counsel, but also to Purdue's then-medical director, and directly to members of the Sackler Families involved in the management of the company, including Richard Sackler, Jonathan Sackler, and Kathe Sackler.

142. Purdue, Richard Sackler, Jonathan Sackler, and Kathe Sackler were thus all aware of the risk and abuse potential and reality of OxyContin long before Purdue acknowledged the same to government, the healthcare community or the public. In sworn testimony before the U.S.

House of Representatives in 2001, Purdue President Michael Friedman, in the presence of Purdue General Counsel Howard R. Udell, swore that the first the companies knew of widespread abuse of OxyContin was in the year 2000. This was, of course, patently inconsistent with what the members of the Sackler Families knew from the Sara memo they had received in 1999. No member of the Sackler Families at any time tried to correct the false narrative promulgated far and wide about the abuse liability of OxyContin, nor corrected the false statement about when Purdue became aware of this problem with the drug.

143. Richard Sackler, Kathe Sackler, Jonathan Sackler, Theresa Sackler, Mortimer D.A. Sackler, and Ilene Sackler have been aware since at least 1999 of potential liability for Purdue, and those acting in concert with Purdue, because of the addictive nature of OxyContin. With the intention of shielding from creditors the proceeds of their wrongdoing, they have stripped out of Purdue and the Purdue-related Additional Defendants each and every year hundreds of millions of dollars of profits from the sales of OxyContin and other opioid-containing medications, including a generic form of OxyContin sold by Rhodes Pharma. All such transfers were and are fraudulent within the meaning of applicable fraudulent transfer statutes and case law; all such transfers unjustly enriched the recipients; and all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid-related liabilities of the companies from which they were transferred.

(6) **The Purdue-Related Additional Defendants Continued to Oversee Purdue's Wrongdoing Even after Purdue Was Fined and Warned about Its Conduct**

144. From 2001 to 2007, Purdue was investigated by 26 states and the U.S. Department of Justice. Beginning in or about 2003, advised by Baker, who served as legal counsel to the entire Purdue organization and the Sackler Families, all of the Sacklers who served as executive officers of Purdue resigned out of concern that they might be held personally

liable for conduct on behalf of Purdue in which they had previously engaged and in which they expected and intended to continue to engage after their respective resignations.

145. In 2007, PFC agreed to pay nearly \$700 million and pleaded guilty to a felony for misleading doctors and patients about opioids. Purdue admitted that its supervisors and employees, “with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.” At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids.

146. As part of the plea agreement in 2007, Purdue agreed to a detailed Corporate Integrity Agreement with the U.S. government. The Agreement required Purdue to appoint a Compliance Officer who would “be a member of senior management of Purdue,” “make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors,” and “be authorized to report on such matters to the Board of Directors at any time.” The Corporate Integrity Agreement was built on the idea that the directors would ensure that Purdue never deceived doctors and patients again.

147. The Corporate Integrity Agreement included the directors as “Covered Persons” from 2007 through 2012. All Covered Persons, including the directors and CEO, were required to comply with rules that prohibit deception about Purdue opioids. The directors were required to undergo hours of training to ensure that they understood the rules. The directors were required to report all violations of the rules. The directors were warned that they could face

consequences if they failed to comply with the rules. The directors certified that they had read and understood the rules and would comply with them.

148. The directors were acutely aware of their obligations under the Corporate Integrity Agreement because, in 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services that it had not immediately trained a new director on the Agreement. Purdue reported: “a new Director was appointed to Purdue’s Board of Directors, without timely notice to either Corporate Compliance or the Office of General Counsel, as otherwise required by policy, resulting in failure to timely launch the training assignment to this new Board member.” Purdue assured the U.S. government that it had trained the new director: “Relevant personnel were reminded of existing policy to notify Corporate Compliance and the Office of General Counsel of changes to the Board of Directors. In both instances, these individuals completed their training assignments within 1 day of Corporate Compliance learning of this issue.” Purdue promised the government that the director’s training had addressed “the proper methods of promoting, marketing, selling, and disseminating information about Purdue’s products,” so Purdue would never deceive doctors and patients again.

149. Every year since the 2007 guilty plea and Corporate Integrity Agreement, Purdue’s directors received warning signs about Purdue’s ongoing misconduct and opportunities to stop it.

150. In 2008, more Americans died from opioid overdoses than ever before.

151. In 2009, the *American Journal of Public Health* published an article about Purdue’s opioid marketing entitled, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy.” The article detailed Purdue’s use of sales representatives,

targeting of high-prescribers, and deception about addiction. That same year, CDC reported that deaths from opioids had recently tripled.

152. In 2010, *Time* magazine published a story about Purdue’s opioids entitled, “The New Drug Crisis: Addiction by Prescription.” Overdoses were the leading cause of accidental death in 15 states. By the spring of 2010, Purdue’s directors had been told that Purdue could not get product liability insurance to cover OxyContin.

153. In 2011, the White House announced that prescription drug abuse was the nation’s fastest-growing drug problem and called for “educating healthcare providers about prescription drug abuse … so they will not over-prescribe[.]” The CDC announced that prescription opioid overdoses had reached epidemic levels and called out Purdue’s opioids by name. That same year, *Fortune* magazine interviewed Purdue executives, including Vice President Alan Must. *Fortune* published a story about Purdue, the Sackler Families, and evidence that they profited from opioid addiction. Mr. Must admitted that Purdue was “well aware” of concerns about its conduct: “We are well aware of detractors. For those individuals who think we’re evil … I don’t think there’s anything we can do that is going to change their opinion.”

154. In 2012, the U.S. Senate launched an investigation into whether Purdue was deceiving doctors and patients about opioids. In a letter to the CEO of Purdue, the Senators warned of “an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers.” The Senate letter warned Purdue specifically of the danger of patients taking higher doses: “over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses.” The Senate letter also warned about Purdue misleading

doctors and patients: “There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs’ safety and effectiveness.” The Senate put the directors on notice that they were under scrutiny, demanding that Purdue produce to investigators a set of “presentations, reports, and communications to Purdue’s management team or board of directors from 2007 to the present.”

155. In 2013, the *Los Angeles Times* revealed that Purdue had been compiling a list for the past decade of 1,800 doctors suspected of recklessly prescribing its opioids, but Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she signed Purdue’s 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said Purdue would not agree to disclose it to authorities because, “I don’t really want to open up an opportunity for folks come in here and start looking and second-guessing.”

156. Abrams and Purdue’s directors knew they had reason to fear scrutiny. The state of Kentucky was prosecuting a lawsuit against Purdue for deceiving doctors and patients about opioids. Purdue’s lawyers surveyed residents who could be on the jury. One-third knew someone who overdosed or was seriously hurt taking a Purdue opioid, and 29 percent knew someone who died. Purdue itself filed those statistics in court.

157. In 2014, Edward Mahony, the Executive Vice President, CFO, and Treasurer of Purdue stated that the Kentucky lawsuit was so significant that it could “jeopardize Purdue’s long-term viability.” That same year, the Governor of Massachusetts declared the opioid crisis a public health emergency.

158. In 2016, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to try to stop dangerous opioid prescribing.

159. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

160. PPI's directors knew or should have known about these warnings and many others.

161. The directors knew about, allowed, and directed Purdue's deception. They oversaw Purdue's scheme to send sales representatives to visit doctors thousands of times. They oversaw Purdue's scheme to hire top prescribers to promote its opioids. They oversaw Purdue's effort to get more patients on higher doses of opioids for longer periods. They were aware of, allowed and directed the content of the messages conveyed in Purdue's marketing.

162. The directors of PPI controlled PPLP. The quarterly reports distributed to the directors of PPI demonstrate that the directors in fact controlled both PPI and PPLP. The reports and minutes make clear that the directors of PPI were kept fully informed of the activities of Purdue in the areas "Finance," "Sales & Marketing," "Manufacturing & Supply Chain," "Quality," "Research & Development," "Discovery Research," "Licensing & Business Development," "Corporate Compliance," "External Affairs," "Health Policy," "Human Resources," and "Information Technology" — all of which were overseen by the directors.

163. The directors oversaw Purdue's sales representatives. Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. He testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force. The board tracked the exact number of sales representatives and the exact number of visits they made to urge doctors to prescribe Purdue opioids. The board knew

which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue; and the company’s plan for sales visits in each upcoming quarter. The Board approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales “territories” in which representatives would target doctors.

164. The directors oversaw the tactics that sales representatives used to push opioids. A board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to “16.7 minutes in front of the customer.”

165. The directors oversaw promotional claims that representatives presented to doctors during sales visits. They received reports, for example, that a “review of call notes” recorded by Purdue sales representatives “suggested potential comparative claims of superiority of Purdue products relative to competitors,” and deceptive promotion of opioids as treatment for “minor pain,” including hundreds of examples of deceptive marketing that required “extensive remedial actions.”

166. The directors oversaw Purdue’s research, including research that contradicted its marketing. The board received reports about studies of Purdue opioids in “opioid-naïve” patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

167. The directors oversaw Purdue’s improper response to signs of “abuse and diversion” by high-prescribing doctors. The board was told exactly how many “Reports Of Concern” Purdue sales representatives submitted to the company about doctors they visited to promote opioids (572 Reports Of Concern in the July 2007 board report); how many “field inquiries” Purdue had decided to conduct in response to the reports (21 inquiries in response to

572 Reports Of Concern); and even that six Reports Of Concern were submitted in Massachusetts.

168. The directors even monitored sales representatives’ emails. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue’s misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an “investigation” and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

169. The directors also oversaw Purdue’s strategy to pay high prescribers to promote Purdue opioids. A report for the board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors: “We are tracking the prescribing trends of these attendees following the programs and will report the results in future reports.” The board was told the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs. The board was told that Purdue would allow a “spending limit for gifts” of \$750 per doctor per year; and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs. The board was told explicitly that paying doctors to promote opioids was “a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities.” When Congress required disclosure of drug company payments to doctors, the board was told there were “significant compliance implications” for Purdue.

170. The directors also oversaw Purdue’s strategy to push patients to higher doses of opioids — which are more dangerous, more addictive, and more profitable. The board routinely

received reports on Purdue’s efforts to push patients to higher doses. A report alerted the board that “Net sales of the 40 and 80 mg strengths of OxyContin” had fallen below Purdue’s targets in the fall of 2010 and were \$85 million below budget. By summer, the board learned that income was \$500 million below budget “mainly due to declining sales in 40 mg and 80 mg strengths. By fall, the board reviewed an assessment that Purdue had lost more than \$800 million in revenue because patients weren’t taking enough 40 mg and 80 mg doses. The board dug into the issue. Multiple reports to the board identified as a “threat” an initiative by public health authorities to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day. The CEO and directors oversaw Purdue’s effort to push back against that public health “threat.” Executives were pleased to report to the directors in 2013 that “initiatives to validate increased total daily doses are having impact in the field.”

171. The directors also oversaw Purdue’s scheme to use higher doses of opioids to keep patients on drugs for longer periods of time. The board received detailed reports of how many patients stayed on Purdue’s opioids for long periods (for example, longer than 35 days), along with Purdue’s internal research showing that getting patients on higher doses keeps them on the drugs longer — all of which puts patients at greater risk of addiction and death. The board received the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose “influences patient length of therapy.” The results showed that patients on the highest doses “are the most persistent.” The “Recommended Actions” presented to the board included “additional workshops for the sales force” and “specific direction” to the sales representatives about using higher doses to keep patients on drugs longer.

172. The board was told in writing that encouraging higher doses “is a focal point of our promotion,” and that sales representatives would “emphasize the importance” of increasing

patients' opioid doses, as soon as 3 days after starting treatment. The board even tracked specific sales materials, such as "two new patient profiles designed to improve patient identification and titration" – to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time. The board was told the exact research behind the sales strategy: higher doses would keep patients on drugs longer because Purdue had found that "83% of patients who discontinued were never titrated to higher doses." The directors knew or should have known that Purdue's sales strategy was deceptive and that putting patients on opioids at higher doses and for longer periods increased the risk of addiction, overdose, and death.

173. The directors also oversaw Purdue's strategy of using "savings cards" to get patients on Purdue opioids for longer periods. The board knew how many thousands of cards were used each quarter, how the company calculated the Return On Investment, and that the explicit goal of the program was to hook patients to "remain on therapy longer."

174. The directors also oversaw Purdue's strategy to target prescribers who did not have special training in opioids (primary care doctors, nurse practitioners, and physician assistants) because they "show the highest responsiveness" to Purdue's sales push. Purdue continued that strategy even though the DEA had expressed concern that Purdue was promoting opioids to clinicians who were not adequately trained in pain management. The directors also oversaw Purdue's strategy to target elderly patients by promotion "targeted to HCPs that practice in the long term care setting," even down to the details of advertising that "leverages images of older patients." The directors knew or should have known that Purdue's sales strategy was deceptive and that targeting primary care doctors and elderly patients increased the risk of addiction, overdose, and death.

175. The directors also oversaw Purdue’s push to steer patients away from safer alternatives. They tracked the company’s effort to emphasize “the true risk and cost consequence of acetaminophen-related liver toxicity.” The board even oversaw Purdue’s deceptive websites, and received reports about the specific section that was found to be deceptive by the New York Attorney General.

176. The directors also oversaw Purdue’s response to signs that patients were being harmed. Reports of harm came in by the hundreds and even thousands. One board report explained that “in excess of 5,000 cases with alleged adverse events have already been received and processed by Drug Safety and the Litigation Support group” during a single quarter.

177. Each of the reports described above was sent to every Sackler Defendant on the board at the time they were prepared.

178. Stuart Baker also received all of the reports described above.

B. The Retail Chain Pharmacies Failed to Control the Supply Chain and Prevent Diversion

179. The Retail Chain Pharmacies earned enormous profits by flooding the country with prescription opioids.

180. The Retail Chain Pharmacies are all engaged in the business of selling opioids at retail. The failure of the Retail Chain Pharmacies to effectively monitor and report suspicious orders of prescription opioids at the retail level and to implement measures to prevent diversion through improper prescriptions greatly contributed to the vast increase in opioid overdose and addiction.

181. The Retail Chain Pharmacies’ conduct directly caused a public health and law-enforcement crisis across this country, including in Kentucky.

(1) The Retail Chain Pharmacies Have a Duty to Prevent Diversion

182. Each of the Retail Chain Pharmacies does substantial business throughout the United States. This business includes the distribution and retail sales of prescription opioids.

183. The Retail Chain Pharmacies distributed and sold at retail substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in New York. In addition, they distributed and sold at retail substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Kentucky. The Retail Chain Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

184. Each participant in the supply chain of opioid distribution, including the Retail Chain Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

185. As sellers of substances known to be dangerous and addictive, the Retail Chain Pharmacies owe a common law duty to act with care in selling at retail these dangerous drugs. In particular, because the risks to public health of uncontrolled distribution of these substances are well-known, the Retail Chain Pharmacies are obliged to use reasonable care to prevent diversion of dangerous drugs.

186. Defendants' common-law duties parallel their obligations under state and federal law, which inform, and provide the standard of care for, these common law duties.

187. The Retail Chain Pharmacies, like manufacturers and wholesale distributors, are registrants under the federal Controlled Substances Act ("CSA"). 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of

controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

188. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

189. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

190. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

191. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

192. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Retail Chain Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

193. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

(2) The Retail Chain Pharmacies Failed to Perform Their Duties

194. Despite their legal obligations under the common law (and under the CSA), the Retail Chain Pharmacies failed to meet their obligations and allowed widespread diversion to occur—and they did so knowingly.

195. The Retail Chain Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

196. The Retail Chain Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

197. The Retail Chain Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

198. The Retail Chain Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

199. The Retail Chain Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

(3) **The Retail Chain Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids**

200. The Retail Chain Pharmacies were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers. Yet, instead of taking any meaningful action to stem the flow of opioids into communities and prevent diversion, they continued to participate in the oversupply and profit from it.

201. The Retail Chain Pharmacies developed and maintained extensive data on opioids they distributed and sold in their retail stores. Through this data, Retail Chain Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of

prescription opioids in communities throughout the country, and in Kentucky in particular. They used the data to evaluate their own sales activities and workforce. The Retail Chain Pharmacies also provided other defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The Retail Chain Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

(4) Retail Chain Pharmacies' Policy of Speed over Accuracy was Negligent.

202. Performance metrics and prescription quotas adopted by the Retail Chain Pharmacies for their retail stores contributed to their failure to perform their duties.

203. The performance metric systems rate the pharmacist employees at the stores operated by Retail Chain Pharmacies based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

204. The Retail Chain Pharmacies measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Retail Chain Pharmacies' locations require pharmacists to fill one prescription every three minutes. The programs may also measure how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing retail defendants' profits.

205. In addition to the pharmacist's other duties, Retail Chain Pharmacies required their employee pharmacists to fill more than 600 prescriptions per work shift.

206. For example, CVS maintains a "Metrics System" to evaluate performance in its pharmacists. Under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists

are calculated, in part, on how many prescriptions that pharmacist fills within a year. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacists are able to fill within a year.

207. At the same time that Retail Chain Pharmacies increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

208. Retail Chain Pharmacies' high-volume and increased-profits business model led to a greater number of errors in dispensing prescriptions, which can result in substantial harm to pharmacy customers.

209. A survey conducted by the Institute for Safe Medication Practices ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, and that 49% felt specific time measurements were a significant contributing factor.

210. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription work flow—using such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

211. The practices of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions at a pharmacy.

212. The Retail Chain Pharmacies productivity policies are directly at odds with their performance of due diligence obligations required to be performed in conjunction with federal and state law, especially given the higher duty of care associated with the prescription of narcotic opioids.

213. The Retail Chain Pharmacies were negligent in failing to ensure, or even permit, pharmacists in their stores to exercise the reasonable care necessary under the circumstances to detect and prevent diversion.

(5) The Retail Chain Pharmacies Failed to Train Employees or Audit Data Regarding Opioid Diversion and Misuse

214. The Retail Chain Pharmacies failed to adequately train their pharmacists and pharmacy techs on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phone, false, forged, or otherwise illegal.

215. The Retail Chain Pharmacies failed to instruct their pharmacists and pharmacy techs on how to address situations in which they are forced to decline filling a prescription for a customer who submitted a prescription which a pharmacist has identified as suspicious.

216. The Retail Chain Pharmacies have failed to train their pharmacists and pharmacy techs on how to properly exercise their judgment with respect to determinations about whether a prescription is one that should be filled, or whether, under the law, the pharmacists should refuse to fill it.

217. The Retail Chain Pharmacies failed to adequately use data available to them to identify doctors that were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids.

218. The Retail Chain Pharmacies failed to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that contributed to the opioid crisis. The Retail Chain Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

219. The Retail Chain Pharmacies failed to conduct internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly.

220. The Retail Chain Pharmacies failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

(6) The Retail Chain Pharmacies Violated the Controlled Substances Act

221. The Retail Chain Pharmacies violated the Controlled Substances Act by failing to have in place policies and procedures to avoid the diversion of opioids.

222. The Retail Chain Pharmacies failed to speak with prescribing physicians prior to dispensing opioids.

223. The Retail Chain Pharmacies failed to take steps such as investigating whether a prescription was written within a prescriber's scope of practice.

224. The Retail Chain Pharmacies failed to investigate whether an opioid prescription was appropriate for the diagnosis.

225. The Retail Chain Pharmacies failed to investigate whether a therapeutic regimen is within the standard of care.

226. The Retail Chain Pharmacies failed to investigate and consider the length of an opioid prescription prior to dispensing.

227. The Retail Chain Pharmacies failed to review State Prescription Drug Monitoring databases prior to dispensing.

228. The Retail Chain Pharmacies failed to abide by internal company policies in the dispensing of opioids.

(7) Multiple Enforcement Actions against the Retail Chain Pharmacies Confirms their Compliance Failures.

229. The Retail Chain Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Retail Chain Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Retail Chain Pharmacies.

230. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Retail Chain Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

231. The litany of state and federal actions against the Retail Chain Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations that govern the distribution and dispensing of prescription opioids.

232. Throughout the country and in the Plaintiff's geographical area in particular, the Retail Chain Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

233. From the vantage point of their retail pharmacy operations, the Retail Chain Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into the Plaintiff's geographical area and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

234. The Retail Chain Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Plaintiff's community.

235. Because of (among other sources of information) regulatory and other actions taken against the Retail Chain Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Retail Chain Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

236. The Retail Chain Pharmacies' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

(a) *CVS*

237. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations.

238. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

239. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

240. This fine was preceded by numerous others throughout the country.

241. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

242. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

243. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the

state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

244. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

245. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

246. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

247. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

248. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

249. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

250. CVS has had knowledge and/or notice of the opioid problem since at least 2002.

251. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

(b) *Walgreens*

252. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

253. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black market sales.

254. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

255. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

256. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the CSA or the health of communities.

257. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

258. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).

259. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

260. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

(c) *Rite Aid*

261. With approximately 4,600 stores in 31 states and the District of Columbia, including 133 in New York, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

262. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.

263. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

(8) Opioids Diverted in One Location Migrate to Others

264. The Retail Chain Pharmacies' failure to control the supply chain and prevent diversion adversely affected communities throughout the United States. Once diverted opioids do not stay put. Rather, diverted opioids move from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

265. First, prescriptions written in one state may, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another. When authorities in some states cracked down on opioid suppliers, suppliers in other states filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

266. Thus, once diverted into the illegal market in one location, prescription opioids could then flow freely into Kentucky and elsewhere. In particular, the I-95 corridor was one route by which diverted prescription opioids travelled from Florida northward to other states.

267. For this reason, the Retail Chain Pharmacies' negligence in failing to prevent in diversion in Florida, and throughout the United States, substantially contributed to the opioid crisis in Kentucky.